PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Fred T. Lee, Jr.	Docket No.:	1512.166
Serial No.:	10/796,239	Filed:	March 9, 2004
Examiner:	David M. Shay	Group Art Unit:	3735

Confirmation No.: 2156

Title: Multipolar Electrode System for Volumetric Radiofrequency Ablation

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DECLARATION OF DIETER HAEMMERICH
TRAVERSING GROUNDS OF REJECTION
UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Dieter Haemmerich, Ph.D, am one of the inventors in the above-entitled U.S. patent application.

2. In 2003, I was awarded a Ph.D. in Electrical and Computer Engineering, Vienna University of Technology, Austria. In 2001, I was granted a Ph.D. in Biomedical Engineering, University of Wisconsin-Madison. In 2000, I was awarded a Masters of Science in Biomedical Engineering, University of Wisconsin-Madison. In 1998, I was awarded an M.S. (Dipl.Ing.) Electrical and Computer Engineering, Vienna University of Technology, Austria. I am a member of the following professional associations: IEEE (Institute of Electrical and Electronics Engineers); EMBS (Engineering in Medicine and Biology Society); STM (Society for Thermal Medicine); HRS (Heart Rhythm Society) and ISCAS (International Society for Computer Aided Surgery).

3. Since June 2008, I have the position of Associate Professor, Div. Pediatric Cardiology, Medical University of South Carolina. Since May 2008, I have also been the Director of the Pediatric Cardiology Bioengineering Program at the Medical University of South Carolina and since September 2004, I have also been an Adjunct Associate Professor, Dept. Bioengineering, Clemson University. From Sept. 2004 – June 2008, I held the position of Assistant Professor, Div. Pediatric Cardiology, Medical University of South Carolina. From Feb. 2003 – Aug. 2004, I held the position of Assistant Scientist, Dept. Surgery, University of Wisconsin-Madison.

4. I am a joint inventor on two (2) issued U.S. Patents as follows:

U.S. Pat. No. 7,367,974 for "Electrode Array for Tissue Ablation"; and
U.S. Pat. No. 7,520,877 for "Radiofrequency Ablation System using Multiple Prong Probes".

I am also named as an inventor on six pending U.S. applications in the field of radiofrequency ablation and a number of corresponding foreign applications.

5. I have authored or co-authored more than 42 peer-reviewed articles published in professional journals including the following :

1. **Haemmerich D**, Staelin ST, Tungjitkusolmun S, Lee Jr FT, Mahvi DM, Webster JG. "Hepatic bipolar radio-frequency ablation between separated multiprong electrodes". *IEEE Trans Biomed Eng* 48:1145-1152, 2001.

2. Cao H, Vorperian VR, Tungjitkusolmun S, Tsai J-Z, **Haemmerich D**, Choy YB, Webster JG. "Flow effect on lesion formation in radiofrequency cardiac catheter ablation". *IEEE Trans Biomed Eng* 48:425-433, 2001.

3. **Haemmerich D**, Tungjitkusolmun S, Staelin ST, Lee Jr FT, Mahvi DM, Webster JG. "Finite element analysis of hepatic multiple probe radio-frequency ablation". *IEEE Trans Biomed Eng* 49:836-842, 2002.

4. Tungjitkusolmun S, **Haemmerich D**, Cao H, Tsai J-Z, Choy YB, Vorperian VR, Webster JG. "Modeling bipolar phase shifted multielectrode catheter ablation". *IEEE Trans Biomed Eng* 49:10-17, 2002.

5. Tungjitkusolmun S, Staelin ST, **Haemmerich D**, Tsai J-Z, Cao H, Webster JG, Lee Jr FT, Mahvi DM, Vorperian VR. "Three-dimensional finite element analyses for radio-frequency hepatic tumor ablation". *IEEE Trans Biomed Eng* 49:3-9, 2002.

6. **Haemmerich D**, Ozkan O, Tsai J-Z, Staelin ST, Tungjitkusolmun S, Mahvi DM, Webster, JG. "Changes of electrical resistivity of swine liver after occlusion and postmortem". *Med Biol Eng Comput* 40:29-33, 2002.

7. Tsai J-Z, Will JA, Van Stelle SH, Cao H, Tungjitkusolmun S, Choy YB, **Haemmerich D**, Vorperian VR, Webster JG. "Error analysis of tissue resistivity measurement". *IEEE Trans Biomed Eng* 49:484-494, 2002.

8. Tsai J-Z, Will JA, Van Stelle SH, Cao H, Tungjitkusolmun S, Choy YB, **Haemmerich D**, Vorperian VR, Webster JG. "In vivo measurement of swine myocardial resistivity". *IEEE Trans Biomed Eng* 49:472-483, 2002.

9. Choy YB, Cao H, Tungjitkusolmun S, Tsai J-Z, **Haemmerich D**, Vorperian VR, Webster JG. "Mechanical compliance of the endocardium". *J Biomech* 35:1671-1676, 2002.

10. Consiglieri L, dos Santos I, **Haemmerich D.** "Theoretical analysis of the heat convection coefficient in large vessels and the significance for thermal ablative therapies". *Phys Med Biol* 48:4125-4134, 2003.

11. Lee Jr FT, **Haemmerich D**, Wright AS, Mahvi DM, Sampson LA, Webster JG. "Multiple probe radiofrequency ablation: Pilot study in an animal model". *J Vasc Interv Radiol* 14:1437-1442, 2003.

12. **Haemmerich D**, Wright AS, Mahvi DM, Lee Jr FT, Webster JG. "Hepatic bipolar radiofrequency ablation creates lesions close to blood vessels – A Finite Element study". *Med Biol Eng Comput* 41:317-323, 2003.

13. Nakada SY, Jerde TJ, Warner TF, Wright AS, **Haemmerich D**, Mahvi DM, Lee Jr FT. "Bipolar radiofrequency ablation of the kidney: Comparison with monopolar radiofrequency ablation". *J Endourol* 17:927-33, 2003.

14. **Haemmerich D**, Staelin ST, Tungjitkusolmun Tsai J-Z, Webster JG, Mahvi DM. "In Vivo electrical conductivity of hepatic tumours". *Physiol Meas* 24:251-260, 2003. (*"Highly downloaded paper" 2004: 585 downloads*)

15. **Haemmerich D**, Chachati L, Wright AS, Mahvi DM, Lee Jr FT, Webster JG. "Hepatic radiofrequency ablation with internally cooled probes: Effect of coolant temperature on lesion size". *IEEE Trans Biomed Eng* 50:493-500, 2003.

16. Lai YC, Choy YB, **Haemmerich D**, Vorperian VR, Webster JG. "Lesion size estimator of cardiac radiofrequency ablation at different common locations with different tip temperatures". *IEEE Trans Biomed Eng* 51:1859-1864, 2004.

17. da Rocha AF, dos Santos I, Nascimento FAO, **Haemmerich D**, Valvano JW. "Effects of the time response of the temperature sensor on thermodilution measurements". *Physiol Meas* 26:885-901, 2005.

18. Pareek G, Wilkinson ER, Schutt DJ, Will JA, Warner TF, **Haemmerich D**, Mahvi DM, Nakada SY. "Hemostatic partial nephrectomy using bipolar radiofrequency ablation". *Br J Urol* 96:1101-1105, 2005.

19. **Haemmerich D**, Webster JG. "Automatic control of finite element models for temperature-controlled radiofrequency ablation". *Biomed Eng Online* 4:42, 2005.

20. **Haemmerich D**, Schutt DJ, dos Santos I, Webster JG, Mahvi DM. "Measurement of temperature-dependent specific heat of biological tissues". *Physiol Meas* 26:59-67, 2005.

21. **Haemmerich D**, Lee Jr FT, Schutt DJ, Sampson LA, Webster JG, Mahvi DM. "Large-volume radiofrequency ablation of Ex Vivo bovine liver with multiple cooled cluster electrodes". *Radiology* 234:563-568, 2005.

22. Laeseke PF, Sampson LA, **Haemmerich D**, Fine JP, Tatum TM, Winter TC, Lee Jr FT. "Multiple-electrode RF ablation: Simultaneous production of separate zones of coagulation in an In Vivo porcine liver model". *J Vasc Interv Radiol*, 16:1727-1735, 2005.

23. **Haemmerich D**, dos Santos I, Schutt DJ, Webster JG, Mahvi DM. "In-vitro measurement of temperature-dependent specific heat of liver tissue". *Med Eng & Phys*, 28:194-197, 2006.

24. Shah J, dos Santos I, **Haemmerich D**, Valvano JW. "Instrument to measure the heat convection coefficient on the endothelial surface of arteries and veins". *Med Biol Eng Comput,* 43:522-27, 2005.

25. Laeseke PF, Sampson LA, **Haemmerich D**, Fine JP, Tatum TM, Winter TC, Lee Jr FT. "Multiple-Electrode
RF ablation creates confluent areas of necrosis: in vivo porcine liver results". *Radiology*, 241:116-124, 2006.

26. Saul JP, **Haemmerich D**. "Comparison of electrode cooling between internal and open irrigation in radiofrequency ablation lesion depth and incidence of thrombus and steam pop" (Letter). *Circulation*, 113:e936, 2006.

27. **Haemmerich D**, Wood BJ, "Hepatic radiofrequency ablation at low frequencies preferentially heats tumor tissue", *Int J Hyperthermia*, 22:563-74, 2006.

28. Pilcher TA, Sanford AL, Saul JP, **Haemmerich D**, "Convective cooling effect on cooled-tip catheter compared to large-tip catheter radiofrequency ablation", *PACE*, 29:1368-1374, 2006.

29. Wood BJ, Locklin J, Viswanthan A, Kruecker J, **Haemmerich D**, Cebral J, Sofer A, Cheng R, McReady E, Clearly K, McAuliffe MJ, Glossop N, Yanof J. "Technologies for guidance of radiofrequency ablation in the multimodality interventional suite of the future", *J Vasc Interv Radiol*, 18:9-24, 2007.

30. Meredith K, **Haemmerich D**, Qi C, Mahvi D, "Hepatic resection but not radiofrequency ablation results in tumor growth and increased growth factor expression", *Ann Surg*, 245:771-6, 2007.

31. Schramm W., Wood BJ, **Haemmerich D**, "Contribution of Direct Heating, Thermal conduction and perfusion during radiofrequency and microwave Ablation", *The Open Biomed Eng J*, 1:47-52, 2007.

32. **Haemmerich D**, Schutt DJ, "Sequential activation of multiple grounding pads reduces skin heating during radiofrequency tumor ablation", *Int J Hyperthermia*, 23:555-66, 2007.

33. Pilcher TA, Saul JP, Hlavacek AM, **Haemmerich D**, "Contrasting effects of convective flow on catheter ablation lesion size: cryo versus radiofrequency energy", *PACE*, 31:300-7, 2008.

34. Schutt DJ, O'Rourke AP, Will JA, Webster JG, Mahvi DM, **Haemmerich D**, "An electrode array that minimizes blood loss for radiofrequency-assisted hepatic resection", *Med Eng Phys*, 30: 454-9, 2008.

35. Schutt DJ, **Haemmerich D**, "Sequential Activation of a Segmented Ground Pad Reduces Skin Heating During Radiofrequency Tumor Ablation: Optimization via Computational Models", *IEEE Trans Biomed Eng*, 55: 1881 – 9, 2008.

36. dos Santos I, **Haemmerich D**, Pinheiro CS, da Rocha AF, "Effect of variable heat transfer coefficient on tissue temperature next to a large vessel during radiofrequency tumor ablation", *Biomed Eng Online*, 7:21, 2008.

37. Schutt DJ, **Haemmerich D**, "Effects of variation in perfusion rates and of perfusion models in computational models of radiofrequency tumor ablation", *Med Phys*, 35: 3462 - 70, 2008.

38. dos Santos I, Correia D, Soares AJM, Goes JA, da Rocha AF, Schutt DJ, **Haemmerich D**, "A surgical device for radiofrequency ablation of large liver tumours", *Physiol Meas*, 29:N59-N70, 2008.

39. dos Santos I, **Haemmerich D**, Schutt DJ, da Rocha AF, Menezes LR, "Probabilistic finite element analysis of radiofrequency liver ablation using the unscented transform", *Phys Med Biol*, 54:611-25, 2009.

40. Schutt DJ, Berjano EJ, **Haemmerich D**, "Effect of electrode thermal conductivity in cardiac radiofrequency catheter ablation: a computational modeling study", *Int J Hyperthermia*, 25: 99-107, 2009.

41. **Haemmerich D**, Schutt DJ, Wright AW, Webster JG, Mahvi DM, "Electrical conductivity measurement of excised human metastatic liver tumours before and after thermal ablation", *Physiol Meas*, 30:459-466, 2009.

42. Schutt DJ, Swindle MM, Helke KL, Bastarrika GA, Schwarz F, **Haemmerich D**, "Sequential Activation of Ground Pads Reduces Skin Heating During Radiofrequency Ablation: In Vivo Porcine Results", *IEEE Trans Biomed Eng*, in press, 2009.

In addition I have authored two book chapters on the topic of tumor ablation:
1. Chapter "Tissue Ablation" in Wiley Encyclopedia of Medical Devices and Instrumentation, 2nd Ed., John Wiley & Sons, 2006
2. Chapter "Radiofrequency Ablation", in book "Image-Guided Therapy Systems", Artech House Publishing, 2009.

6. I have reviewed the Office action of October 7, 2009, in which Claims 1-9, 13- 16-22, 28 and 29 have been rejected principally over Gough et al., U.S. Pat. No. 5,728,143 (Gough et al. '143 patent) and Swanson, U.S. Pat. No. 6,488,679. From the front page of the Gough et al.'143 patent, I am advised that as of 1998 at the time the patent issued, Gough et al. was assigned to Rita Medical Systems, Inc., Mountain View, California.

7. In particular, I have been requested to comment on the Examiner's findings at page 2, lines 8-16 of the Office action, that it would have been obvious (at the time of the invention) to provide each shaft as an insulated metal tubular member in a coaxial configuration, and to provide an insulated portion of the trocar between two sets of antennae which I understand is recited in pending claim 16, last three lines.

8. I understand that Claim 28 includes the matter recited in claim 16 from which it depends. I understand from reviewing the Reply to the Final Action of June 24, 2009, that Claim 16 recites:

> 16. (Previously presented) An electrode assembly for ablating tumors in a patient comprising:
>
> (a) a shaft configuration comprising a first support shaft and a second support

shaft, the first support shaft having an electrically insulated outer surface;

(b) a first electrode set having at least three electrode tips radially extensible from the first support shaft at a first position to three respective radial points defining a first plane surrounding the first support shaft;

(c) a second electrode set having at least three electrode tips radially extensible from the second support shaft to three respective radial points defining a second plane surrounding the second support shaft at a second position that is axially displaced along the first support shaft from the first position by a predetermined distance, said predetermined distance being predetermined in a kit before insertion into the patient by a physician, wherein the second plane is opposite the first plane and is separated from the first plane by a predetermined separation to define a three-dimensional volume of tissue to be ablated between the first plane and the second plane; and

(d) wherein when bipolar power is applied to the first electrode set and to the second electrode set, electrical current flows between the first plane and the second plane and through the three-dimensional volume of tissue; and

wherein a portion of the shaft configuration that extends from the first position to the second position is insulated so as not to drain current from the volume of tissue being ablated.

9. I understand that claim 28 adds the following subject matter to claim 16:

wherein the first support shaft has a tubular metal inner portion and an insulated outer portion and wherein the second support shaft has a tubular metal inner portion and an insulated outer portion and wherein the first support shaft is disposed within the second support shaft to provide a concentric tube configuration.

10. I was familiar with Rita Medical equipment on the market as of the year 2000, because we used Rita equipment to make our prototypes of our invention. The Rita Medical equipment could not be used, however, without significant modification.

11. The following is a sketch of a Rita Model 30 probe, which can be referred to as an electrode set, as of the year 2000:

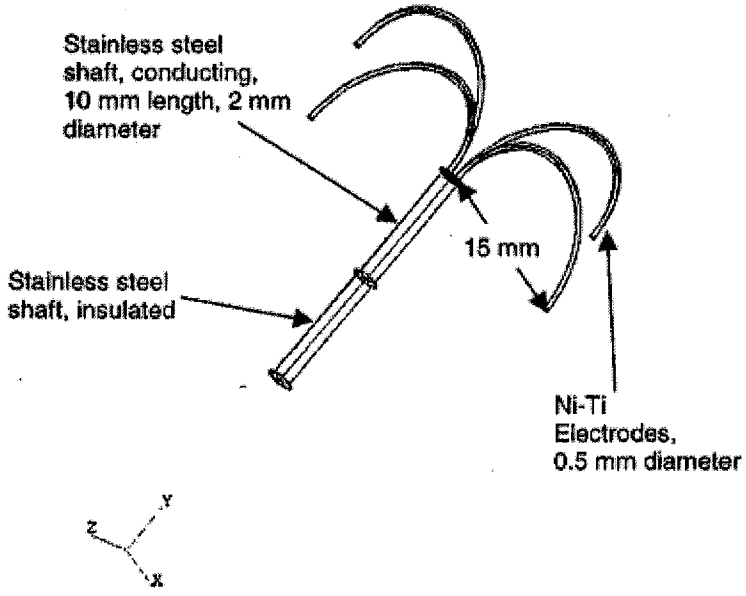


Fig. 1. Geometry of fully deployed Rita model 30 umbrella probe used in FEM. The prongs and the distal 10 mm of the shaft conduct RF current. The orientation of the coordinates is shown at the bottom.

Please note that the upper portion of the shaft is uninsulated while the lower portion is insulated.

12. In these probes power was applied between at least one electrodes and a grounding pad as shown in Fig. 2 below.

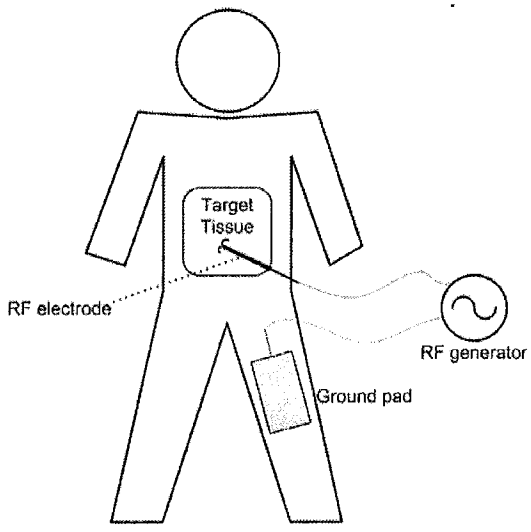
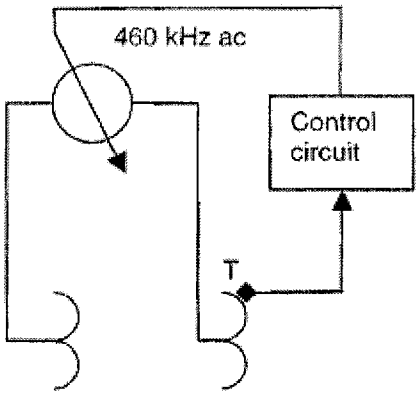


Fig. 2. Schematic of Rita Model 30 Probe

13. In the year 2000 there were not any devices with multiple electrode sets that were commercially available from Rita Medical or others known to us. In the year 2000, we used two commercial Rita Medical electrode sets (type model 30). Note that these electrode sets were designed to be used one set at a time. To use these electrode sets, modifications were made to insulate an upper end portion of the shaft of one of the electrode sets where it is extended beyond the shaft of the other electrode set. Also, power was applied between the two electrode sets rather than between one electrode of the electrode set and a grounding pad (this is how this electrode set was designed to be used). We utilized two Rita probes (electrode sets) in a circuit in which the power supply was connected between them to supply bipolar power as shown below, but that the number of electrodes per set was more than two when performing volumetric ablation.



14. There was nothing in the product offerings of Rita Medical that would advise us or suggest to us that two electrode sets could or should be used together, or that bipolar power could or should be applied between two electrode sets or that the portion of one shaft extending beyond the other shaft should be insulated or that one shaft could be inserted in the shaft of a separate Rita electrode set to provide a coaxial configuration or that two electrode sets could be used in a side-by-side configuration. In fact, all known radiofrequency ablation devices available in the year 2000 required a grounding pad, and there was no known commercial device of this type available for operating in bipolar mode at that time. Therefore, I see nothing that would support the Examiner's finding referred to in paragraph 7 above, based on the knowledge of one of ordinary skill actually practicing in this art in the year 2000.

15. I have also reviewed the Gough et al., U.S. Pat. No. 5,728,143, and particularly col. 7, lines 21-30, which reads as follows:

> As illustrated in FIG. 2, trocar 14 is introduced into a selected tissue mass 28. Three or more antennas 16 are positioned within a trocar lumen as trocar 14 is introduced into and through the selected tissue mass. In various embodiments, 3, 4, 5, or 6 antennas 16 are introduced laterally through trocar 14. Subsequently, antenna distal end 16' is advanced out of aperture 26 into selected tissue mass 28. Insulation sleeves 18 are adjusted for antennas 16. RF, microwave, short wave and the like energy is delivery to antenna 16 in a monopolar mode (RF), or alternatively, multiple antenna device 12 can be operated in a bipolar mode (RF).

One of ordinary skill in the art in the year 2000 would not conclude that this was referring to using two electrode sets. One of ordinary skill in the art would conclude that this power delivery was between antennas in the same electrode set or between the antennas and a grounding pad as seen in the Rita Model 30 probe diagrammed above.

16. I have also reviewed Gough et al., U.S. Pat. No. 5,728,143, and particularly Figs. 7 and 8, and col.7, lines 21-34 , and the remainder of the Gough et al. reference, and it is not described in a manner that would have been understandable by one of ordinary skill in the art at the time that the power supply of Fig. 9 or any other power supply, is connected between two electrode sets such as the electrode set in the insulating sleeve 18, and the electrode set in trocar 14 to apply bipolar power between two electrode sets as claimed in claims 16 and 28 set forth above.

17. I have also reviewed the Examiner's findings at page 6, lines 14-22, that

Gough et al (' 143) also teach that when multiple antennae are used, they can produce "a substantially complete ablation volume formed between antennas 16 with a minimal core that is not ablated" (see Figure 4, and column 8, lines 2-4), as one of ordinary skill in the art would readily appreciate, the only way a non-ablated core can be produced is if there is no current flowing between the antennae and the trocar, and this would enable one of ordinary skill in the art to conclude that the trocar is insulated to produce this effect.

Still further, Gough et al (' 143) also teach that when multiple antennae are used, the antennae may be situated at different axial positions along the trocar and "can be operated in a bipolar mode between the two antennas 16,or between a antenna 16 and trocar 14" (see Figure 5, and column 5, lines 9-11).

18. Referring now to the first finding in paragraph 17 above, in reviewing Gough et al (' 143), all instances of reference number 14 refer to a trocar that is uninsulated at its upper end as shown in the cross section in Fig. 6c. When an insulating sleeve is added, it always has reference number 18. This is consistent with the known construction of the Rita Model 30 in the year 2000 as shown above in Fig. 1. It cannot concluded that the upper end of trocar 14 in Fig. 4 is insulated from the descriptions of the embodiment of Fig. 4, particularly col. 8, lines 1-4. In fact, it would not be possible to obtain the heating zone shown as dashed ellipse in Fig. 4 if trocar 14 was insulated. Similarly, Fig. 8 shows a trocar without insulation 18 between the upper and lower antennas, and there is nothing suggesting existence of such insulation.

As to the second finding in paragraph 17 above, Fig. 5 shows only one antenna in each spaced apart position, such that the trocar must be rotated to ablate a volume of tissue. That does not suggest two electrode sets each having a tubular metal inner portion and an insulated outer portion and wherein the second support shaft has a tubular metal inner portion and an insulated outer portion and wherein the first support shaft is disposed within the second support shaft to provide a concentric tube configuration as recited in claim 28 set forth above. It also does not suggest such elements in combination with paragraph (d) of claim 16, wherein when bipolar power is applied to the first electrode set and to the second electrode set, electrical current flows between the first plane and the second plane and through a three-dimensional volume of tissue.

19. For similar reasons, the above cited readings of Gough et al. in the Office action do not make obvious the subject matter of claim 29, which recites wherein the first support shaft is positioned in a side-by-side configuration with the second support shaft in the context of two electrode sets as recited in claim 16 as recited above, which is incorporated by reference in claim 29. The employment of two support shafts allows improved positioning of the two electrode sets depending on tumor geometry and location.

20. Once the Gough et al. '143 patent is properly understood in view of the commercial embodiments of its assignee known in the period from 1995 to 2000, the findings in the Office action referred to above are not reasonable readings of what one of ordinary skill

in the art would understand from the Gough et al. reference and there is nothing added by Swanson, U.S. Pat. No 6,488,679 that alters that conclusion.

21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 12/14/2009 By: Dieter Haemmerich

Dieter Haemmerich, Ph.D.